Food and Drug Administration
Center for Drug Evaluation and Research

'99 AUG 30 P3:12

SUMMARY MINUTES
ARTHRITIS ADVISORY COMMITTEE

February 20, 1998
Holiday Inn Bethesda
8120 Wisconsin Avenue, Bethesda, MD

Members Present
Michelle Petri M.D., M.P.H.,Chair
Steven B. Abramson, M.D.
Barbara C. Tilley, Ph.D.
Harvinder Luthra, M.D.
Frank Pucino, Jr., Pharm.D.
E. Nigel Harris, M.D.
Matthew Liang, M.D., M.P.H.

FDA Participants
Michael Weintraub, M.D.
Kent R. Johnson, M.D.
James P. Witter, M.D.
Jeffrey N. Siegel, M.D.
William D. Schwieterman, M.D.

Consultants
Felix Fernandez-Madrid, M.D., Ph.D.
Barbara White, M.D.
Larry Moreland, M.D.
Leigh Callahan, Ph.D.

Guest Experts
Marlene Egger, Ph.D.

Members Absent
David Yocum, M.D.
Daniel Lovell, M.D., M.P.H.
Lee Simon, M.D.
Leona Malone, MSW

Executive Secretary
Kathleen R. Reedy

These summary minutes for the February 20, 1998 meeting of the Arthritis Advisory Committee were approved on 8/26/99.

I certify that I attended the February 20, 1998 meeting of the Arthritis Advisory Committee and that these minutes accurately reflect what transpired.

Kathleen R. Reedy,
Executive Secretary

Michelle A. Petri, M.D., M.P.H.
Chairperson

The Arthritis Advisory Committee met on February 20, 1998 at the Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD to discuss a Proposed Document: Guidance for Industry: Clinical Development Programs for Drugs, Devices and Biological Products Intended for the Treatment of Osteoarthritis (OA). The committee had been provided a briefing document from the agency as background approximately 15 days before the meeting. There were approximately 200 people in attendance.

The meeting was called to order at 8:00 by Michelle Petri, M.D., Chair of the Arthritis Advisory Committee. The Meeting Statement was read by Kathleen Reedy, Executive Secretary of the Arthritis Advisory Committee. The Committee members and consultants introduced themselves. A welcome and introduction to the topic by Michael Weintraub, M.D., Acting Director, Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products began the discussion. Kent R. Johnson, M.D., Medical Officer, presented the draft of the proposed Document.

There were two speakers at the Open Public Hearing. Steven Geis, M.D., Executive Director, Clinical Research at Searle spoke of standards for trials. John F. Beary III, M.D., Medical Director of Arthritis Research at Procter and Gamble spoke of linking claims to pain relief. Paul Varady of Dimethaid Research, Inc. submitted a letter which was read.

The committee discussion was conducted around the following topics, in the order they appear in the draft document.

Claims
- Pain
- Function
- Structure
- Durability
- Delay in New OA Development
- Delay in Surgical Joint Development
- Other Claims

Trial Analyses
- Assembling the Evidence
- Risk-Benefit Assessment

These questions were addressed with discussion by the committee.

1. Is the overall claim structure appropriate?
2. In OA trials of novel new agents, is it worth trying to *capture* under the randomized rubric a broader assessment than suggested above? This might be done, for example, by formally defining outcomes described by the patient to include toxicity considerations and to aim to have an endpoint closer to the full risk/benefit expression.

3. Is there a more elegant way to capture *nonsignal joint* activity? Given its strong rationale, should it matter that there is *no* experience using such a measurement?
4. Should time be an explicit requirement for *any* claim, or should limitations in the data simply be reflected in labeling?
5. Should *pain improvement* and *function improvement* be combined into one claim?
6. Is it best to leave unspecified *how much* clinical evidence of pain or function improvement is needed for a structure claim?
7. Are there insurmountable obstacles, which will make designs for the claims *delay in new OA development* and *delay in surgical joint replacement* fatally flawed?

A verbatim transcript of the meeting is available for more detailed examination of the discussion issues. The discussion and consensus will be taken into consideration and incorporated in the next draft of the proposed Guidance for Industry: Clinical Development Programs for Drugs, Devices and Biological Products Intended for the Treatment of Osteoarthritis (OA) Document.

The meeting was adjourned at approximately 4:15 pm.